Speakers

Dr Raphael Bar
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EU GMP-/FDA-compliant Sampling

19 – 21 May 2021 | Berlin, Germany

EU GMP-/FDA-compliant Sampling Plans with Efficient Procedures and Reduced Sampling

Highlights

- Regulatory and compendial requirements around sampling
- Acquaintance with basic sampling distributions
- √N rule: its uses and misuses
- Acceptance Sampling Plans in ISO-2859-1/ANSI Z1.4
- WHO requirements for sampling
- Classification, Charting and Trending of nonconformities
- Understanding the risks of producer and consumer associated with the sampling plans
- Sampling and inspection of packaging materials
- How to effectively reduce the amount of samples to be tested?
- Sampling for visual inspection of particles in drugs
- Sampling of Powders (APIs and Excipients) and tools for sampling in a pharmaceutical plant
- Good quality practice around sampling plans
- Reference and Retention Samples

Objective

The aim of this course is to discuss the process of the statistical sampling of

- finished drug products
- packaging materials (primary and secondary)
- medical devices
- starting materials (APIs and excipients)

and to define the prerequisites for implementing a system for reduced sampling and reduced testing for these products.
This course is also intended to give a practical training on the use of the most common sampling standards: ISO 2859-1:1999 and ANSI/ASQ Z1.4. Starting with regulatory and compendial requirements around sampling, this course will also address

- charting and trending nonconformities and nonconformant items
- good quality practice around sampling plans
- Reference and Retention Samples

The course participants will learn how to read and to use the standards for selecting a sampling plan with an understanding of the associated producer and consumer risks.

Background

Sampling of materials is one of the most important processes in pharmaceutical companies. Today there are **more and more detailed questions during regulatory GMP Inspections, both in Europe and in the US (FDA) about the amount of samples to be taken.**

Sampling by Attributes is a process of inspecting a representative sample of identical product units of product for presence or absence of nonconforming units or nonconformities before accepting or rejecting the whole lot of product. Regulatory agencies require a sampling plan that utilizes basic elements of statistical analysis or provide a scientific rationale for taking a representative sample according to the lot size. In the light of these regulatory requirements, one may wonder whether the Square Root of N is a statistically valid sampling plan.

According to the revised Chapter 6 of EU GMP Guide, the sampling plan used should be appropriately justified and based on a risk management approach.
Representative samples should be taken and recorded in accordance with approved written procedures.

FDA requires as well in the Code of Federal Regulations (21 CFR Part 211.84), that sampling should be done upon statistical criteria.

In the past the Military Standard 105 D was commonly used in the pharmaceutical industry, but this standard has been withdrawn and is now obsolete. Today, either the ISO Standard 2859:1-1999 or the ANSI Z1.4 are applied. These Standards are widely employed in various types of industries which are required by Regulatory Authorities to follow a statistically sound sampling plan.

Target Audience

This GMP Education Course is directed at all those employees from quality control units and production units in the pharmaceutical industry who are competent or responsible for sampling, testing and release of starting materials (APIs and excipients), packaging materials (primary and secondary) as well as finished pharmaceutical products. This course is also of interest to personnel from quality assurance and to those employees from API, excipient or packaging material suppliers who want to inform themselves about the requirements of the pharmaceutical industry on the testing of these materials.

The course does not require prior knowledge in sampling and statistics. It teaches the participant how to use the multiple tables and plots of the Standard for designing a sampling plan.

Relevant tables from the

ISO Standard ISO 2859-1:1999
Sampling procedures for inspection by attributes
Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

will be made available to the course participants for the purpose of practicing.

Programme

Regulatory and compendial requirements around sampling

- History of sample taking and sampling
- Sampling plans
- Regulations: US GMPs, EU GMPs, WHO, PIC/S
- Articles sampled in pharma and bio-tech (discrete units vs. granular or liquid materials)

Acquaintance with basic sampling distributions

- What is Acceptance Sampling:
- Sampling Attributes vs. sampling by variables
- Nonconforming items and nonconformities
- Hypergeometric distribution
- Binomial distribution
- Poisson distribution
- Normal distribution
- Concept of probability of acceptance

√N rule: its uses and misuses

- Origin of the rule
- Uses and misuses
- How confident is it?

Acceptance Sampling Plans in ISO-2859-1/ANSI Z1.4

- Structure of the Standards
- Single sampling Plan
- Double sampling Plan

- Multiple sampling Plan
- Switching rules between Normal-Tightened-Reduced inspections
- Producer and consumer risks
- Acceptance sampling of an isolated lot using ISO-2859-2

Workshop I

Step-by-step use of ISO-2859-1/ANSI Z1.4
- Procedure for a Single sampling Plan (Exercises)
- Procedure for a Double sampling Plan (Exercises)
- Procedure for a Multiple sampling Plan (Exercises)
- Exercise in using tables of sampling

Sampling according to the WHO Guide

- Sampling of starting materials
- Full testing vs. testing for identity
- Qualified supplier vs. unreliable supplier
- n, p and r plans
- Criticism of the sampling plans

Classification of nonconformities and allocating AQL to classes

- Classification schemes
- Classification of nonconforming items (Class A, B, C...)
- Classification of nonconformities (Class A, B, C...)
- Examples of nonconformities in pharmaceutical preparations (Optional)
- Allocating AQL to various classes

Charting and trending nonconformities and nonconforming items

- Run chart and control chart
- Charting the number of defectives
- Charting the number of nonconformities
- Detecting a trend in your inspection quality
- Determining your process average
- Does your inspection data confirm your AQL?
- Deriving statistically your allowed percent defectives

Risks in sampling with ISO-2859-1/ANSI Z1.4

- Probability of acceptance
- Producer risk
- Consumer risk
- Operating Curve
- Misconceptions of sampling
- Determining product and consumer risks in a sampling plan

Practicing with Producer and Consumer risks in sampling with ISO-2859-1

Sampling and inspection of packaging materials

- Regulations and guidance for packaging and labeling control
- Primary packaging: containers and closures:
  - What is inspected?
  - AQL for sampling
  - Defects in PPMs
- Secondary packaging: labels, leaflets and folded boxes:
  - What is inspected?
  - AQL for sampling
  - Sampling in printing house
  - Sampling in manufacturer's site
  - Defects in labels

How to effectively reduce the amount of samples to be tested?

- Reduced Testing concepts
- Internal testing vs. external testing
- Using the suppliers CoA instead of in-house testing
- Use of devices to reduce amount of samples (Rapid ID testing, Rapid Mibi Testing)

Workshop II

Implementing Reduced Testing
- Exercise implementation of reduced testing concepts on real life examples

Sampling for visual inspection of particles in parenteral drugs

- Regulations for sampling for visual inspection
- Types of sampling
- AQL for sampling
- Policy of sampling and inspection

Sampling of Powders (APIs and Excipients)

- Regulatory requirements
- Risk assessment for sampling
- Sampling plans / sampling schemes
- Training for sampling
- Retention / Reference samples
- Starting material Identity testing
- Sampling for the purpose of Assay
- Sampling of raw materials (WHO guide, n/r/p-sampling plans)

Tools for Sampling in a pharmaceutical plant

- Techniques of drawing samples
- Prerequisites / Requirements for correct sampling
- Sampling devices and containers

Good quality practice around sampling plans

- How to document the sampling system within the company?
- How to incorporate it into specifications (FDP/raw materials)?
- How to incorporate it into the LIMS system?
- What you should discuss with the supplier! (tailgate samples, pre-delivery shipment samples, statements of homogeneity)

Reference & Retention Samples

- What samples need to be taken
- Regulations on reference, retention & reserve samples
- Quantities to be taken
- Retention periods

Speakers

Dr Raphael Bar
BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society for Analytical Chemistry. For the lasts ten years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Dr Gerald Kindermann
AGIDENS AG, Switzerland

Dr Kindermann was Product Quality Manager at the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality Control and Quality Manager for the Supply Center. Since August 2019 he works as a Senior Pharma Consultant at AGIDENS AG in Switzerland.

Philip Lienbacher
Takeda, Austria

Mr Lienbacher is Manager Global Material Lifecycle Management Systems and is responsible for a team of process experts and project managers. His responsibility includes the global ownership for Receiving & Inspection as well as the general testing and method deployment-strategy in the company.

Date
Wednesday, 19 May 2021, 9.00 – 18.00
(Registration and coffee 8.30 – 9.00)
Thursday, 20 May 2021, 9.00 – 18.00
Friday, 21 May 2020, 9.00 – 13.30

Venue
HYPERION Hotel Berlin
Prager Straße 12
10779 Berlin, Germany
Phone +49 (0)30 236250-0
hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event on the first day, lunch on the first and second day, business lunch on the third day and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Social Event


In the evening of the first day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
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For questions regarding reservation, hotel, organisation etc. please contact:
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On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-(0)6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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Reservation Form (Please complete in full)

EU GMP-/FDA-compliant Sampling, 19 – 21 May 2021, Berlin, Germany

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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